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Predictors of Treatment Completion and Study Retention of Smokers Across Three Population-Based, Tailored Multiple Risk Behavior Interventions

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PREDICTORS OF TREATMENT COMPLETION AND STUDY RETENTION OF SMOKERS ACROSS THREE POPULATION-BASED, TAILORED MULTIPLE RISK BEHAVIOR INTERVENTIONS

BY

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ABSTRACT

Dropout from both smoking treatment and research study participation is often problematic and can negatively affect treatment and research outcomes respectively. The current study examined baseline predictors of both treatment and research phase completion in a combined dataset of 3 parallel, population-based studies targeting multiple health behaviors. Baseline variables were examined for associations with treatment and research completion (defined as completing the final time points respectively). Results from the multivariate model for the treatment phase (1-year from baseline) indicated that those who were divorced were 36% less likely to complete than non-divorced (OR = .64, 95% CI = .49, .84, p < .01). The treatment group was 35% less likely to complete compared to the control group (OR = .65, 95 % CI = .54− .79, p < .0001) and the patient sample was 1.3 times more likely to complete than non-patients (OR = 1.30, 95 % CI = 1.04 − 1.63, p < .05). Each year of education was associated with a 9% increase in the chance of completion (OR = 1.09, 95% CI = 1.05, .1.15, p < .0001). Results from the multivariate model for the research phase (2-years from baseline) varied slightly from the treatment phase analysis. Similar to treatment, those divorced were 35% less likely to complete than non-divorced (OR = .65, 95% CI = .50, .84, p < .01), the treatment group was 38% less likely to complete than the controls (OR = .62, 95% CI = .51, .74, p <.0001), and each year of education was associated with a 9% increase in the chance of completion (OR = 1.09, 95% CI = 1.05, 1.14, p <.0001). Differing from the treatment phase, being in the patient sample was not significant, but those in the in the worksite sample were 26% less likely to complete (OR = .74, 95% CI = .56, .98, p < .05). Additionally, Hispanics were 52% less likely to complete the research phase compared to non-

Hispanics (OR = .48, 95% CI = .23, .98, $p < .05$) and each 24-hour quit attempt was associated with a 4% decrease in the chance of completion (OR = .96, 95% CI = .93, .99, $p < .05$). These findings could inform future investigations in this area, a line of research that may be of high interest for the development of recruitment and retention methods.

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CHAPTER 1

INTRODUCTION

Cigarette smoking continues to be the leading cause of preventable death in the United States, accounting for approximately 480,000 deaths each year (National Center for Chronic Disease Prevention and Health Promotion (US) Office on Smoking and Health, 2014). Despite decades of focus on smoking cessation by both government and private agencies, an estimated 45.3 million adults (19.3%) continue to smoke cigarettes (CDC, 2011a). Although the number of smokers has been in general decline since the 1960's when approximately 42.4% of adults were smokers, the past 20 years show a much slower decline and a decrease of only about 6% over that span (CDC, 2011b).

Despite the slowing decline in the number of adult smokers, 68.8% of adult smokers report that they want to quit completely and in 2010 over half (52.4%) were able to quit at least once for 24-hours (CDC, 2011c). Methods for cessation vary and may include brief clinical contact (e.g. primary care recommendation and assistance), cessation counseling, behavioral therapies, medication, nicotine replacement therapy, or a combination of different interventions. However, even the best interventions generally have a modest 1-year abstinent rate below 30%. Further, and specific to the aim of this study, treatment non-completion and study dropout factor into the efficacy and evaluation of these interventions respectively.

Multiple studies have shown that treatment adherence rates correlate positively with tobacco abstinence. Hood, Ferketich, Paskett, and Wewers (2013) found that adherence to behavioral counseling was positively associated with cessation outcomes in a combined behavioral and NRT intervention. Hays, Leischow, Lawrence, and Lee (2010) found that adherence to pharmacological treatment was highly correlated with improved tobacco abstinence. This finding is specifically interesting because it was true regardless of treatment assignment in the study (i.e. active drug vs. placebo). Nerin and colleagues (2007) found similar results in a multi-component smoking cessation therapy in which participants with poor adherence had a lower probability of continued abstinence at 6 months. Linke, Rutledge, & Myers (2012) found that retained participants achieved a cessation rate of 26.1% compared to only 15.7% of all enrolled participants. Both Foulds et al. (2006) and Hood, Ferketich, Paskett, and Wewers, (2013) noted the predictive ability of cessation treatment compliance in positive treatment outcomes. These findings support the value of treatment attendance as a mechanism for successful cessation treatment.

Dropout rates from longitudinal research is an area that has received a lot of attention from a methodological perspective, but less attention from a treatment outcome perspective. As a result, much of the literature related to dropouts is focused on the impact of missing data and how to manage it instead of a close examination of why the data is missing or if it could have been prevented. Regardless, missing data are not uncommon in longitudinal studies and this may be specifically true for participants with substance abuse (Collins & Seitz, 1994; Nich & Carroll, 2002; Yang

& Shoptaw ,2005). Even the most stringent recruitment and randomization methods can inadvertently lead to a biased sample if dropout rates are not random.

This study aims to add to this literature by investigating both treatment completion and the retention of smokers in research studies by using a combined dataset from 3 multiple health risk behavior studies utilizing an expert system intervention. The specific goal is to identify which baseline variables might predict a higher risk of treatment and/or research non-completion. Significant results will add to the body of literature examining who is more likely to dropout from treatment and research studies.

CHAPTER 2

REVIEW OF LITERATURE

Specific research investigating predictors of dropout in smoking studies is lacking, as few studies have examined this. A key issue in the research of treatment dropout and research study dropout is the lack of a commonly accepted definition of a drop out. For example, Fernández, López, and Becoña (2010) investigated premature dropout from smoking treatment among individuals diagnosed with a personality disorder and defined dropout as attending less than half the sessions. In contrast, Cluss, Levine, and Landsittel (2011), defined dropout as only attending one session and considered all others as completers in a study of low-income, pregnant smokers. Regardless of the specific definition decided upon by the researchers, we can assume that each definition was chosen because the researchers believed their definition had an impact on the results. However, the variation in definition across studies is a barrier to examining dropouts.

Research attempting to identify participant-level demographic variables that are predictive of dropout in a broader group of health behavior studies has yielded mixed results to date. Younger age was shown to be predictive of retention in an adolescent smoking study by Kalkuis-Beam and colleagues (2011). However, other studies have found that younger age is associated with dropout in adult populations (Hays, Leischow, Lawrence & Lee, 2010; Leeman et al., 2006). Results of other studies that focused on weight loss and general lifestyle interventions have also suggested that

younger age is associated with discontinuation (Bautista-Castaño, Molina-Cabrillana, Montoya-Alonso, & Serra-Majem, 2004; Schultz et al., 2012; Moroshko, Brennan, & O'Brien, 2011).

Sex is another variable with mixed predictive results. The results of the studies by Bautista-Castaño et al. and Schultz et al., illustrate a conflict on gender with the former showing that males responded better and the latter showing that being male predicted dropout. Curtin, Brown & Sales (2000) reported that females were less likely to attend the post-inclusion initial assessment. Other studies found no significant difference between males and females (Hays, Leischow, Lawrence & Lee, 2010; Siddiqui, Flay, & Hu, 1996). As of this writing, no studies examined the potential predictive nature of LGBTQ populations to our knowledge.

Previous research has suggested that retention is predicted by being assigned to a less demanding control group as well as being unemployed suggesting that schedules and time demands could play a notable role in dropouts (Lee, Hays, McQuaid, & Borelli, 2010; Kalkhuis-Beam et al. 2011). It is important to note that the studies for the current analysis did not include any in-person appointments (phone only) and that time points were spread out over 6-month intervals. The majority of research in this area has focused on more intensive interventions including in-person contacts.

Brogan, Prochaska J.O., & Prochaska J. M. (1999) found no significant predictors from static client characteristics, but were still able to correctly classify 92% of the cases into premature terminators or appropriate terminators and continuers in a psychotherapy setting. Dynamic variables such as stage of change, process of change,

and decision making defined the discriminant function suggesting that such variables that are open to change and we have included them here.

Smoking severity related variables have been shown to be predictive of dropout in smoking studies. Gadomski, Adams, Tallman, Krupa, & Jenkins (2011) found that higher levels of nicotine dependence and number of cigarettes regularly smoked were both associated with increased odds of dropping out. A study looking at predictors of dropout from the Lung Health Study also found smoking severity variables to be a significant predictor of dropout (Snow, Connett, Sharma, & Murry, 2007).

The current study expands on this research by examining both treatment and study completion in the context of a population-based study. To our knowledge, this is the first study to examine predictors of both treatment and study completion in such a large smoking intervention. Additionally, this study may offer a unique perspective on treatment retention as the intervention was a stage-based expert system report delivered via mail. The studies cited here were not population-based, had in person contact, and more frequent contact.

CHAPTER 3

METHODOLOGY

Participants

This study involved a secondary data analysis of a combined data set from three population-based studies. Each study intervened on multiple health risk behaviors and all three included smoking, diet, and sun exposure. Additionally, one study also included regular mammography relapse while another included exercise. The focus of this analysis was limited to those participants who received the smoking intervention and were included regardless of whether they were also received additional interventions for diet, sun exposure, mammography, or exercise. A final combined dataset included 2263 baseline smokers recruited from 3 sites described below.

The largest sample was recruited from a primary care site and was facilitated by a large health insurance provider. 12,978 patients were contacted by phone about participation in a multiple risk expert system intervention study. Of the 8,564 that agreed to participate, 5,407 were eligible and were at risk for at least one health risk behavior including smoking, diet, sun exposure, and release from regular mammography. A total of 1211 smokers were identified in this sample and included in this analysis.

Twenty-two schools in Rhode Island taking part in a separate school-based study (see: Prochaska et al. 2004) provided contact information for parents of teens. A total of 3,507 respondents were contacted about participation in a multiple risk expert system intervention for smoking, diet, and sun exposure. Of the 2,921 that agreed to

participate, 2,460 were at risk for at least one of the behaviors and eligible for the study. For the purposes of this proposed analysis, 707 baseline smokers were recruited and will be included.

Twenty-two worksites provided contact information as part of a larger multiple risk behavior study. Eligible employees were at risk for at least one health risk behavior including smoking, diet, sun exposure, and exercise. A total of 345 baseline smokers were identified for inclusion in this proposed analysis (For more information on this sample see Velicer et al., 2004).

Intervention

Interactive stage-based technologies have consistently generated 23% - 25% point prevalence abstinence rates at 18- to 24-month follow ups (Prochaska, DiClemente, Velicer, & Rossi, 1993; Prochaska, Velicer, Fava, Rossi, & Tsoh, 2001; Prochaska, Velicer, Fava, Ruggiero, Laforge, et al., 2001; Velicer, Prochaska, et al., 1999). Such interventions for adults have proven to be both effective and cost effective utilizing only three interactions over a period of 6 to 12 months (Prochaska et al., 1993; Velicer et al., 1993; Velicer & Prochaska, 1999). This has been achieved without in person contact as these interventions and assessments are done telephonically or via mail. Another advantage of stage-based expert system interventions is their ability to produce these results on a population level, which often includes a large percentage of early-stage smokers.

Participants in all three studies were randomized into either the treatment condition (n = 1108) or a control condition (n = 1155). Those assigned to the

treatment condition received an expert system intervention. These three- to five-page reports (for each risk behavior) were divided into five sections: The first section focused on stage of change and readiness to change the behavior. The second section addressed pros and cons of changing, with feedback when necessary about under-evaluating the pros of changing and/or over-evaluating the cons. The third section provided feedback on participants' use of up to six change processes relevant to their stage of change. Participants were compared normatively on each change process with the most successful self-changers. For the two follow-up assessments, they were also compared ipsatively to their prior assessment. The fourth section focused on tempting situations, with feedback on how to enhance self-efficacy in the most tempting situations and the last section consisted of strategies for taking small steps to progress to the next stage.

Participants in the treatment group of all three studies completed assessments at baseline, 6-months, and 12 months either via mail or by telephone. Upon completion of each assessment, participants were mailed expert system reports tailored to their responses to the assessments at each of these time points. Treatment condition participants also completed follow up assessments at 12 and 24 months. Participants in the control group only received the outcome measure assessment at 0, 12, and 24 months and a standard guide to clinical preventative services.

Measures

Baseline Demographics

Gender, age, race and ethnicity, perceived general health, marital status, education level, BMI, and number of persons in the household were available from the baseline data via self-report. The inclusion of these variables will add to the literature and attempt to possibly clarify some of these earlier findings. This study also differs from most of the previous research of demographic variables predictive of dropout in that both the intervention and research placed very low demands on the participants. Unlike many studies that require regular office visits or more frequent assessment, participants in these studies only had three telephonic or mail contacts in the control condition and four in the treatment condition. This analysis of a lower demand research protocol might provide a different perspective on demographic predictors as a result.

Stage of Change, Decisional Balance, and Temptations for Smoking

The stage of change measure for smoking cessation has proven to account for the most variance in previous TTM research and involves an algorithm based on six yes–no questions (DiClemente et al., 1991; Velicer et al., 1992). In order to be eligible for the study, participants had to be in the precontemplation, contemplation, or preparation stage. Precontemplation is defined by not intending to quit in the next 6-months, contemplation by a desire to quit in the next 6 months, and preparation by intending to quit in the next month. Participants had to be in one of these three stages to be included in the study.

The Decisional Balance and Temptation measures combine to account for the second most variance after the stage of change (Velicer, DiClemente, Prochaska & Brandenberg, 1985; Velicer, DiClemente, Rossi & Prochaska, 1990). A predictable

relationship between the Pros and Cons of the Decisional Balance across stages was found in cross sectional studies on 12 health behaviors (Prochaska et al., 1994). Those in precontemplation show higher support for the Pros of smoking than the Cons, while the opposite holds true for those in Action and Maintenance. Temptation to smoke is inversely related to confidence in remaining quit and, similar to the Pros of smoking, have been shown to decrease as one moves from precontemplation to preparation (Velicer et al., 1990). An examination of the Process of Change variables are excluded and outside the scope of this analysis.

Problem Severity/Smoking History Variables

We included the number of cigarettes smoked per day, time to first cigarette, number of 24-hour quit attempts in the past year, and longest quit attempt in this analysis.

Treatment

Participants in all three studies were randomly assigned to either the treatment or control condition. We will include treatment as a potential predictor of dropout to determine if being in the treatment condition had an effect on retention.

Recruitment Site

The combined data set includes participants that were recruited via three different methods, HMO referral list, parents of school children, and worksite program. We included the recruitment site as an independent variable to investigate the role it might have on continued engagement.

Single Versus Multiple Risk Behaviors

The subjects used for this analysis were part of a multiple risk behavior intervention and although we have only included those that were at risk for smoking, some of these participants received additional interventions for diet, sun exposure, regular mammography relapse prevention, and exercise. For this study, the number of behaviors intervened on for each participant ranged from one to three, with all participants being intervened on for smoking.

Definitions of Other Key Terms:

For the purposes of this proposed study "treatment completion" will be defined as the completion of the final treatment contact at 12 months. We also defined research completion as completing the final research follow up assessment at 24 months.

Statistical Analyses

The primary goal of this analysis was to explore which baseline variables, if any, predicted our dependent variables of treatment completion and separately, research completion. We plan to achieve this by conducting an analysis in two phases. In the first phase, we will compute differences on the independent variables between completers and non-completers for the treatment phase and research phase using univariate models. In the second phase, we will select variables that achieve a liberal $p \leq .20$ in the univariate analysis and include them in separate multivariate analyses for each dependent variable

The hypotheses for the first stage of analysis will be tested utilizing independent t-tests for continuous variables or Chi Square tests for categorical variables. Each independent variable will be compared across completers and non- completers for inclusion in stage two. All categorical variables maintained at least 5 participants in greater than 20% of cells (Yates, Moore, McCabe, 1999). The majority of the continuous variables had equal variance between groups, but a few did not. To account for this, Welsh's t-test was used.

The secondary aim of this analysis will be to further explore the significant variables identified in phase 1 by constructing two multivariate prediction models for research dropout and treatment dropout. To test these hypotheses we will utilize logistic regression modeling. We chose this method because we will potentially have a mix of continuous and categorical predictors along with a dichotomous, categorical outcome variable. We used the log-likelihood significance test to evaluate if the model with predictors is best and calculated an effect size (pseudo R^2) using McFadden's ρ^2.

We also conducted a micro-level analysis to explore the individual predictors. To do this we utilized Wald tests for parameter estimates and calculated odds ratios. Results should inform on the predictive ability for each independent variable.

CHAPTER 4

FINDINGS

The racial and ethnic composition of the sample was 94.9% White and 1.8% Hispanic. The mean age was 42.3 years old with an average of 13.3 years of education. Sixty-six percent were either married or living with their partner while 22% were divorced, separated or widowed and the remainder reporting, "not married". The average number of people living in the house was 3.32.

Overall, the sample had a mean body mass index of 24.96% and most reported their perceived health as "good" (41.5%). Others reported their perceived health as "poor" (2.7%), fair (15.5%), very good (32.2%), or excellent (7.9%). They smoked an average of 17.38 cigarettes per day with the majority of the sample smoked their first cigarette in the first 1.5 hours after waking up. The sample averaged 2.23 quit attempts (24 hour minimum) in the past year with 40.5% having zero attempts. The average length of the longest quit attempt for those who made at least one was slightly over 3 years.

The majority of the sample was in the contemplation stage of change (43.4%) with 35.8% in pre-contemplation and 20.7% in preparation. Their average pros and cons of smoking were 2.7 and 3.7 respectively. On the temptation scales, the sample reported highest on negative affect (3.82), lowest on habit strength (2.71), with positive social (3.52) in the middle.

The largest recruitment method was via primary care patients constituting 53.5% of the sample. Parents of a school intervention added 31.2% with the worksite recruitment accounting for the remaining 15.3%. The sample was divided quite evenly with 49% assigned to the treatment condition. The majority of the sample identified with 3 behaviors for change (50.3%), slightly less with 2 behaviors (39.5%), and 10.2% identified for smoking intervention only.

Univariate analysis for treatment completion revealed a number of significant results (See figure 1 for means and standard deviations). Completers were slightly older [t = 2.00 (1244), p = .0448], more likely to be white [X^2 (4, N = 2,162) = 9.987, p = .040], less likely to be Hispanic [*X2* (1, N = 2,187) = 9.528, p = .002], have slightly better perceived health [X^2 (4, N = 2,190) = 6.762, p = .149], more likely to be married or living together [X^2 (5, N = 2,186) = 11.182, p = .048], have more years of education [t = 5.00 (1394), p < .001], less 24 hour quit attempts in the past year [t = -2.07 (1363), p = .038], higher cons of smoking [t = 1.84 (1379), p = .066], and be assigned to the control group [X^2 (1, N = 2,263) = 19.84, p < .001]. The recruitment method also revealed a significant results between the 3 methods with 64.5% completing from the parent study, 71% from the primary care patient study, and just 60% from the worksite study [X^2 (2, N = 2,263 = 18.826, p < .001].

Results from the multivariate model for the treatment phase (1-year from baseline) indicated that those who were divorced were 36% less likely to complete than non-divorced (OR = .64, 95% CI = .49, .84, p < .01). The treatment group was 35% less likely to complete compared to the control group (OR = .65, 95 % CI = .54− .79, p < .0001) and the patient sample was 1.3 times more likely to complete than non-patients (OR = 1.30, 95 % CI = 1.04 − 1.63, p < .05). Each year of education was also

associated with a 9% increase in the chance of completion (OR = 1.09, 95% CI = 1.05, .1.15, p < .0001). The log-likelihood test revealed that the model was indeed a better fit than the empty model [X^2 (22) = 102.32, p < .001] with a medium effect size (McFadden's $\rho^2 = .15$).

The univariate analysis for study completion revealed thirteen significant differences between study completers and non-completers. Being Hispanic [X^2 (1, N = 2,187) = 7.16, p < .05] and less years of education [t = 4.82, (1746), p < .0001] were associated with study dropout, while higher Body Mass Index [t = 1.42, (1676), p < .20] and the number of people living in the household [t = -1.82, (1630), p < .10] were two were associated with study completion. Two smoking variables, lower number of 24 hour quit attempts [t = -2.51, (776), p < .05] and a longer previous quit attempt [t = 1.83, (1910), p < .10], were associated with study completion.

Stage of change [X^2 (2, N = 2,263) = 3.23, p < .05] was significant along with both the pros [t = 1.32, (1762), p < .20] and cons [t = 1.60, (1829), p < .15] of smoking. Three temptation variables were also associated with completion including positive social [t = 2.08, (1820), p < .05], negative affect [t = 1.30, (1771), p < .20], and total temptations [t = 1.87, (1717), p < .10]. Similar to treatment completion, both being assigned to the control condition [X^2 (1, N = 2,263) = 326.89, p < .0001] and the recruitment method [X^2 (2, N = 2,263) = 20.55, p < .0001] were highly associated with study completion.

Results from the multivariate model for the research phase (2-years from baseline) varied slightly from the treatment phase analysis. Similar to treatment, those divorced were 35% less likely to complete than non-divorced (OR = .65, 95% CI = .50, .84, p < .01), the treatment group was 38% less likely to complete than the

controls (OR = .62, 95% CI = .51, .74, p <.0001), and each year of education was associated with a 9% increase in the chance of completion (OR = 1.09, 95% CI = 1.05, 1.14, p <.0001). Differing from the treatment phase however, being in the patient sample was not significant, but those in the in the worksite sample were 26% less likely to complete compared to not being in this sample (OR = .74, 95% CI = .56, .98, p < .05). Additionally, Hispanics were 52% less likely to complete the research phase compared to non-Hispanics (OR = .48, 95% CI = .23, .98, p < .05) and each 24-hour quit attempt was associated with a 4% decrease in the chance of completion (OR = .96, 95% CI = .93, .99, p < .05). It should be noted that the vast majority of the participants that did not complete the 12-month time point also failed to complete the 24-month assessment, likely explaining much of the similarities in the findings. The log-likelihood test revealed that the model was indeed a better fit than the empty model [X^2 (22) = 96.14, p < .001] with a medium effect size (McFadden's $\rho^2 = .14$).

Table 1. *Baseline differences on continuous variables at end of treatment phase*

End of Treatment (12-months)			
	Completers (n= 1524; 67%)	Non-Completers (n=739; 33%)	
	M (SD)		p-value
Age	42.6 (9.9)	41.7 (10.6)	0.045*
Hispanic	1.2%	3.2%	0.002*
BMI	25.01 (4.7)	24.84 (4.7)	0.433
Number of persons in household	3.31(1.4)	3.36 (1.4)	0.408
Education level	13.43 (2.6)	12.87 (2.3)	6.407e-07*
Number of cigarettes smoked per day	17.38 (11.2)	17.38 (11.9)	0.998
Time to first cigarette	2.57 (4.1)	2.64 (4.2)	0.741
Number of 24-hour quit attempts in past	2.14 (2.8)	2.41 (2.8)	0.038*
Longest quit attempt	37.68 (104)	34.40 (91)	0.476
Pros of smoking	2.73 (.85)	2.65 (.92)	0.05*
Cons of smoking	3.71 (.89)	3.63 (.93)	0.066*
Temptations – positive social	3.52 (.88)	3.51 (.90)	0.965
Temptations – negative affect	3.83(.97)	3.82 (1.0)	0.858
Temptations – habit strength	2.7 (.98)	2.71 (1.0)	0.852
Temptations – total	3.35 (.72)	3.35 (.77)	0.973

Table 2. *Baseline differences on categorical variables at end of treatment phase*

End of Treatment (12-months)			
	Completers (n= 1524; 67%)	Non-Completers (n=739; 33%)	
	Percentage		p-value
Race (white)	95.8%	84.4%	.041*
Perceived general health			0.15*
Poor	2.8%	2.6%	
Fair	15.4%	15.9%	
Good	40.4%	43.9%	
Very Good	34.0%	28.7%	
Excellent	7.4%	8.9%	
Marrital status			.048*
Married	62.5%	56.7%	
Not married, living together	4.7%	6.4%	
Not Married	11.9%	12.4%	
Separated	2.9%	3.8%	
Dviorced	14.1%	17.6%	
Widowed	3.9%	3.1%	
Sex (female)	70.8%	68.2%	0.341
Stage			0.545
Pre-Contemplation	35.6%	36.3%	
Contemplation	44.2%	41.9%	
Preparation	20.2%	21.8%	
Treatment	45.7%	55.8%	8.416e-06*
Recruitment method			8.164e-05*
Parent	29.9%	33.9%	
Patient	56.5%	47.4%	
Worksite	13.6%	18.7%	
Health risk interventions			0.524
1 Behavior	11.2%	12.8%	
2 Behaviors	39.1%	38.2%	
3 Behaviors	49.7%	49.0%	

Table 3. *Baseline differences on continuous variables at end of research phase*

End of Research Assessment (24-months)			
	Completers (n= 1366; 60%)	Non-Completers (n=897; 40%)	
	M (SD)		p-value
Age	42.52 (9.89)	41.99 (10.53)	0.249
Hispanic	1.2%	2.9%	0.007*
BMI	25.07 (4.74)	24.77 (4.74)	0.156*
Number of persons in household	3.28 (1.39)	3.39 (1.49)	0.069*
Education level	13.46 (2.50)	12.93 (2.46)	1.583e-06*
Number of cigarettes smoked per day	17.40 (11.22)	17.35 (11.70)	0.923
Time to first cigarette	2.60 (4.2)	2.57 (4.1)	
Number of 24-hour quit attempts in past	2.10 (2.77)	2.42 (3.00)	.012*
Longest quit attempt	39.8 (109)	31.8 (85)	0.068*
Pros of smoking	2.72 (.84)	2.67 (.91)	0.184*
Cons of smoking	3.70 (.89)	3.64 (.92)	0.11*
Temptations – positive social	3.55 (.86)	3.47 (0.90)	0.038*
Temptations – negative affect	3.85 (.95)	3.79 (1.05)	0.194*
Temptations – habit strength	2.72 (.98)	2.69 (1.01)	0.477
Temptations – total	3.37 (0.71)	3.31 (0.78)	0.061*

Table 4. *Baseline differences on categorical variables at end of research phase*

End of Research Assessment (24-months)			
	Completers (n= 1366; 60%)	Non-Completers (n=897; 40%)	
	Percentage		p-value
Race (white)	95.4%	94.2%	0.458
Perceived general health			0.326
Poor	2.8%	2.6%	
Fair	15.4%	15.7%	
Good	41.1%	42.1%	
Very Good	33.6%	30.4%	
Excellent	7.1%	9.2%	
Marital status			0.214
Married	62.4%	58.0%	
Not married, living together	5.1%	5.5%	
Not Married	11.9%	12.2%	
Separated	3.0%	3.5%	
Divorced	13.8%	17.5%	
Widowed	3.8%	3.3%	
Sex (female)	70.0%	69.2%	0.3406
Stage			0.199*
Pre-Contemplation	34.8%	37.5%	
Contemplation	45.0%	41.1%	
Preparation	20.2%	21.4%	
Treatment	44.5%	55.7%	2.16e-07*
Recruitment method			3.44e-05*
Parent	30.3%	32.7%	
Patient	56.8%	48.5%	
Worksite	12.9%	18.8%	
Single versus multiple health risk interventions			0.884
1 Behavior	11.5%	12.1%	
2 Behaviors	39.2%	38.2%	
3 Behaviors	49.3%	49.7%	

CHAPTER 5

CONCLUSION

The current study sought to add to the literature relevant to both treatment and research completion by examining baseline predictors. Few studies have assessed both treatment and research completion with the same sample. The retention rates for the studies included here totaled 67% for the treatment phase and 60% for the research phase, which are slightly lower than some smaller studies assessing smoking cessation treatment and study retention (Lee, et al, 2010). Similar to Lee et al, (2010), this study did not require participants to be interested in quitting to be eligible, thus the samples include those in pre-contemplation and contemplation.

One specific difference between these studies however, was the recruitment method. Lee et al (2010), generally recruited in-person from hospitals, outpatient clinics, flyers, cultural events, and other studies. Most importantly, the present study had no in person contact at all. All recruitment and all assessments were completed via telephone while interventions consisted of only a stage-based expert system report delivered via mail. Other possible differences between these specific studies include follow up effort and participant compensation.

Consistent with previous findings, being in the treatment group was one of the strongest predictors of dropout, raising an interesting dilemma for both clinicians and researchers. There is a notable dose-response relationship between tobacco treatment and it's effectiveness (Elfeddali, Bolman, Candel, Wiers, & de Vries, 2012; Secades-Villa, Alonso-Pérez, García-Robríguez, & Fernández-Hermida,

2009). In-person treatment tends to perform best and the effectiveness is increased with increased intensity (Fiore, 2000). However, studies have also shown that placing more demands on the patient increases the risk of dropout and failed treatment compliance (Lee, Hays, McQuaid, & Borelli, 2010; Kalkhuis-Beam et al. 2011). These results suggest that there may be an optimal treatment dosing that can balance effectiveness and retention.

This seems an important factor when discussing "impact", which is defined as the participation rate multiplied by efficacy (Velicer and DiClemente, 1993). Most research in this area has focused on the reach of an intervention along with the efficacy and problems related to dropout will impact both. For example, smoking studies often assume that non-respondents are smoking and while that is considered an acceptable assumption, increasing study retention would provide more accurate data and minimize the need for assumptions. Furthermore, increasing the treatment retention rate would likely increase the efficacy. Regardless of our ability to increase these rates, future research should carefully consider this in their design.

Interestingly, and unique to this study, there were minimal treatment demands placed on the participants because there were no in-person appointments and contact was generally only every few months. As a result, the intervention was largely driven by participant's own willingness to change and implement recommendations based on their tailored expert system reports. We did not have data available on how much actual time or effort they spent on making changes or whether they actively engaged in other treatment during the course of this study. For example, a participant in the contemplation stage may have been motivated by their expert system report to engage in additional treatment, increasing the demands. Regardless, this type of intervention

offers tremendous opportunity for reach on a population level.

With this in mind, one interesting non-significant finding was that stage of change was not a significant predictor of treatment or study retention. In the univariate analysis of the research phase, stage did achieve a p-value of approximately 0.199, just making the high threshold of .20 to be included in phase 2 of the analysis. However, in a traditional sense, it was not significant for either treatment or study completion. This is notable because it supports previous research suggesting that state-based tailored interventions can effectively retain participants across pre-contemplation, contemplation, and preparation at similar rates (Prochaska et al., 1993; Velicer et al., 1993; Velicer & Prochaska, 1999).

Another notable, non-significant finding related to treatment demands is that the number of behaviors intervened on did not impact dropout rates for either treatment or study completion. This finding supports the clinical outcome research showing that addressing multiple health behavior change sequentially offers no benefit over, and might be superior to, treating them simultaneously (Hyman, Pavlik, Taylor, Goodrick &Moye, 2007; Prochaska, Spring, Nigg, 2008). Practically speaking, this is in an important finding that suggests providers can and should encourage a simultaneous approach to treating multiple health behavior risks.

The findings related to education level, divorce, and being Hispanic are more difficult to interpret without further investigation or collecting additional data. It's possible that the demands placed on participants are at play here as divorced individuals may have more time demands placed on them in other areas like balancing work and childcare. Individuals with higher levels of education may be

less motivated by monetary incentives, possibly affecting their motivation to remain engaged. Hispanic individuals are more likely to have English as a second language and all communications in this study were completed entirely in English.

The differences between the different samples used provide an interesting look at how recruitment pathways might impact retention. Participants recruited through primary care lists provided by an HMO were 1.3 times more likely to complete the treatment phase compared to non-patients. Data was not collected on concurrent treatment, but it seems plausible that these participants felt some additional pressure to remain engaged because they were recruited through their HMO. It's also possible that these participants informed their PCPs, who reinforced their participation in smoking cessation treatment. This theory seems to be supported by the fact that being part of the patient sample was not significant at the end of the research phase. That is, once the treatment phase ended, they were no more likely to complete the research phase than the other samples.

The results suggesting that a higher number of past 24-hour quit attempts decreased the chances of research phase completion could be related to a number of different factors. One might wonder if those with many failed quit attempts could feel more discouraged and feel more embarrassment in reporting that they were not successful. Impulsivity may also be a factor. Those who have more quit attempts likely have an increased number of relapses and here is a relationship between impulsivity and relapse (Bloom, Matsko, & Cimino, 2014). If these are indeed participants with higher levels of impulsivity, it seems plausible that they might be less likely to stay committed to a research study.

When interpreting these results, there are some aspects that should be

carefully considered. First, the sample size was quite large overall (n=2263) creating statistically significant results with relatively minor differences. For example, age was a significant predictor for treatment completion in the univariate analysis ($p < .05$), but the difference in means between completers and non-completers was only .9 years ($r = .04$). While the results were indeed statistically significant, the issue of clinical relevance should be carefully considered.

Another limitation was the definition used to define completion, which was a single interaction at the final treatment/follow up time point. There are pros and cons to the varying definitions discussed earlier in the paper, but we chose this approach because if nothing else, it identifies participants who were engaged to some extent for the entirety of treatment. The decisions was a little easier with regard to study follow up because the final time point is quite vital to most analysis. With regard to additions research, much of the outcome variables can be collected at a later time point and still inform about the intervention.

The current study offers some insight into who is dropping out of treatment and research studies and attempts to identify some specific predictors. These findings could inform future investigations in this area, a line of research that may be of high interest for the development of recruitment and retention methods. Future studies should aim to better understand these predictors and their interactions with each other as well as investigate the clinical significance these findings may have.

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